

### REMARKS/ARGUMENTS

Claims 1-56 are pending. In the claims. Claims 1-56 stand rejected under 35 USC 102 (e) as being anticipated by US patent number 7393957, US patent number 6878713, US patent number 6964966 (all to De Souza).

#### I. Rejection under 35 USC 102 (e)

The Office (through the Examiner) has rejected claims 1-56 under 35 USC 102 (e) as being anticipated by US patent number 7393957, US patent number 6878713, US patent number 6964966 (all to De Souza).

The Examiner contends that De Souza teaches in US patent 73993957 the instantly claimed compounds, salts and polymorphs (see the claims and page 26 line 65). (Office Action, page 2). The Examiner also contends that De Souza in US6878713 teaches the instantly claimed compounds/salts as pharmaceutical compositions and methods of treating bacterial infections. (Office Action, page 2). The Examiner concludes that "The instantly claimed polymorphs, once placed into a pharmaceutical composition which includes water, would lose their special properties as polymorphs. Also, when placed into a body for treatment of infections, the compounds would no longer be special polymorphic forms". (Office Action, page 2). The Examiner also concludes that "Due to this, the compositions and methods of treatment are fully encompassed by the '713 patent. (Office Action, page 2).

Applicants respectfully traverse this rejection and, to the extent they are maintained with respect to the claims as amended herein, request reconsideration and withdrawal of the rejection.

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Page 3 of 8. 10:58 AM. 12/12/2008. Re: response to Office Action mailed on September 12, 2008. Applicants: Prasad Keshav DESHPANDE. Filing Date: 08/21/2006. Application Serial Number: 10/578,371. Examiner: Margaret D SEAMAN. Confirmation Number: 8976  
Mail Stop: Patent Application (non-fee amendment)

Initially, it is noted that the Office action has not identified where in US patent number 7393957, US patent number 6878713, US patent number 6964966 (all to De Souza), the alleged teaching is to be found on all of the limitations of any of Claims 1-56. Still further, Applicants have carefully reviewed the remainder of US patent number 7393957, US patent number 6878713, US patent number 6964966 (all to De Souza), and find no teaching of all of the limitations of any of claims 1-56. Thus, for at least this reason, US patent number 7393957, US patent number 6878713, US patent number 6964966 (all to De Souza), cannot anticipate claims 1-56.

Neither US patent number 7393957 alone or in combination with US patent number 6878713 or US patent number 6964966, discloses all of the limitations of any of claims 1-56. None of the cited prior art reference disclose the specific polymorphs claimed in the instant invention. US patent 6,878,713 and US patent 7,393,957 disclose polymorph A1 and A2. They are not the same.

In general, polymorphism in chemical substances is the ability of a single compound to exist in two or more solid phases, each having different arrangements and/or conformations of the individual molecules in the solid form (D. J. W. Grant, *Theory and Origin of Polymorphism*. In H. G. Brittain (ed.) *Polymorphism in Pharmaceutical Solids*, Marcel Dekker, Inc, New York, 1999, pp. 1-34) (a copy is attached). Different polymorphic forms generally have different chemical and physical properties such as melting point, chemical reactivity, apparent solubility, dissolution rate, stability, processibility etc. It is in this perspective that preparation of a specific polymorph having advantageous properties (compared to rest of the polymorphs) has always been desired.

Applicants submit that the polymorphs claimed in the instant application have not been reported in the prior art, including the references cited by the Examiner. The claimed polymorphs are also different from the prior art polymorphs A1 or A2 disclosed in US 6878713 and US 7393957 (for example, differentiating characteristic of polymorph A-3 are given below):

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Page 4 of 8. 10:58 AM, 12/12/2008. Re: response to Office Action mailed on September 12, 2008. Applicants: Prasad Keshav DESHPANDE. Filing Date: 08/21/2006. Application Serial Number: 10/578,371. Examiner: Margaret D SEAMAN. Confirmation Number: 8976  
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S. No	Differentiating parameter	Polymorph A-1 disclosed in prior art US 6878713 and US 7393957.	Polymorph A-2 disclosed in prior art US 6878713 and US 7393957.	Polymorph A-3 claimed in present patent application
1	Process solvent	Methanol	50% aqueous isopropanol	Aqueous isopropanol
2	Melting point (by DSC)	257.17	253.17°C	257.33°C
3	PXRD spectra (2θ peak)	Unique	Shows peak at 6.7	Peak at 6.7 is absent in PXRD spectra.

Further, it is to be noted that the unexpected results revealed by the claimed polymorphs are in terms of reproducibility at bulk manufacturing, stability and crystallinity which is substantially improved when compared with the prior art polymorphs (A1 and A2).

In rejecting claims 1-56 under 35 U.S.C. § 102 (e), the Examiner concedes that the De Souza US patents, as mentioned above, do not expressly or implicitly teach that once the claimed polymorphs of this invention are placed into a pharmaceutical composition which includes water, would lose their special properties as polymorphs. Also, the statement that when placed into a body for treatment of infections, the compounds would no longer be special polymorphic forms as alleged by the Examiner is not supported by the prior art. (Office Action, page 3). Again, Applicants respectfully traverse this rejection at least because the Office has not met its burden to fully develop reasons supporting this conclusion that the claimed subject matter is anticipated. The Office always bears the initial burden to develop reasons supporting any conclusory statement. (MPEP 2112 (IV)). To satisfy this burden, the Office must identify some basis in fact or articulate some reasoning at least tending to show that any allegedly inherent subject matter necessarily (i.e., inevitability) flows from cited art. Indeed, the MPEP expressly instructs that in relying upon the theory of inherency, for example, the examiner must provide a basis in fact and/or technical reasoning to reasonably support

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Page 5 of 8. 10:58 AM, 12/12/2008. Re: response to Office Action mailed on September 12, 2008. Applicants: Prasad Keshav DESHPANDE. Filing Date: 08/21/2006. Application Serial Number: 10/578,371. Examiner: Margaret D SEAMAN. Confirmation Number: 8976  
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the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Further, since a basis in fact and technical reasoning is required when inherency is invoked, a failure to provide such evidence or rationale is fatal to the reliance on this doctrine. This is only logical since evidence "must make clear" that the allegedly inherent subject matter is necessarily present in (i.e., necessarily flows from) the disclosure of cited art. (MPEP 2112). This naked assertion, a mere conclusory statement, cannot reasonably be said to be a development of any reason supporting the Office's reliance on inherency. Consequently, the Office Action's reliance on inherency is unsupported and thus improper.

In sum, the Office Action concedes that the three US patents cited by the Examiner do not teach the feature of claims 1-56 and any reliance on the doctrine of inherency to provide this necessary teaching is improper. That the compounds may lose their individual character once administered and metabolized or dissolved in the body does not alter the basic characteristic of the material actually being administered. It is that material and not some later derived material which is being claimed herein. Therefore, it is that material which must be described in a prior art reference in order for that reference to anticipate the present claims. Here, the Examiner has not identified a prior art reference which describes or discloses that which is claimed.

The Applicants would like to bring to the attention of the Examiner that the Office must provide specific factual findings predicated on sound technical and scientific reasoning to support this conclusory statement. An Examiner may rely on facts within his or her own knowledge to support a rejection. When relying on personal knowledge, however, the Examiner must provide an affidavit or declaration setting forth specific factual statements and an explanation to support the finding. (MPEP §2144.03(C)). Such an affidavit is subject to contradiction or explanation by the affidavits of the Applicant and/or other persons. (See 37 CFR §1.104(d)(2)).

As noted above that the Office Action fails to specifically address even the expressly recited features of the pending independent and dependent claims. Under the

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Page 6 of 8. 10:58 AM. 12/12/2008. Rc: response to Office Action mailed on September 12, 2008. Applicants: Prasad Keshav DESHPANDE. Filing Date: 08/21/2006. Application Serial Number: 10/578,371. Examiner: Margaret D. SEAMAN. Confirmation Number: 8976  
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Office's policy of compact prosecution, each claim should be reviewed for compliance with every statutory requirement for patentability in the initial review of the application. (MPEP §707.07(g)). It is submitted that the present application is not sufficiently informal, does not present an undue multiplicity of claims, or exhibit a misjoinder of inventions, so as to reasonably preclude a complete action on the merits. Thus, it is submitted that the Office's failure constitutes a failure to expeditiously provide the information necessary to resolve issues related to patentability that prevents the Applicant from, for example, presenting appropriate patentability arguments and/or rebuttal evidence. (See The Official Gazette Notice of November 7, 2003). Additionally, it is submitted that the Office's failure needlessly encourages piecemeal prosecution, which is to be avoided as much as possible. (MPEP §707.07(g)). Accordingly, in the event that the Office maintains the rejection of any of the independent and/or dependent claims, Applicant respectfully requests, in the interests of compact prosecution, that the Office apply art against each feature of each rejected independent and dependent claims, on the record, and with specificity sufficient to support a prima facie case of anticipation.

Again, none of these references teach or suggest each and every limitation recited in the pending claims.

A single prior art reference anticipates a patent claim only if it expressly or inherently describes each and every limitation set forth in the patent claim. *Trintec Industries, Inc. v. Top-U.S.A. Corp.*, 295 F. 3d 1292, 63 USPQ2d 1597 (Fed.Cir.2002); See *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2D 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the....claim. *Richardson v. Suzuki Motor Co.*, CO F. 2d 1226, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Accordingly, this rejection should be withdrawn.

#### Conclusion

Applicants respectfully submit that the patent application is in condition for allowance and notification to that effect is earnestly requested. If desired, the examiner is

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Page 7 of 8. 10:58 AM. 12/12/2008. Re: response to Office Action mailed on September 12, 2008. Applicants: Prasad Keshav DESHPANDE. Filing Date: 08/21/2006. Application Serial Number: 10/578,371. Examiner: Margaret D SEAMAN. Confirmation Number: 8976  
Mail Stop: Patent Application (non-fee amendment)

invited to conduct a telephone conference to expedite the prosecution of the subject application. In such a case, the examiner is invited to call the undersigned attorney.

Should any official at the United States Patent and Trademark Office deem that any further action by the Applicants or Applicants' undersigned representative is desirable and/or necessary, the official is invited to telephone the undersigned at the number set forth below.

The Commissioner is hereby authorized to charge any fees which may be required regarding this application under 37 CFR §§ 1.16-1.17 or credit any overpayment, to deposit account No. 503321. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, or otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 503321.

Respectfully submitted,

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Page 8 of 8. 10:58 AM. 12/12/2008. Re: response to Office Action mailed on September 12, 2008. Applicants: Prasad Keshav DESHPANDE. Filing Date: 08/21/2006. Application Serial Number: 10/578,371. Examiner: Margaret D SEAMAN. Confirmation Number: 8976  
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